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In The
Supreme Court of the United States

ALBERTO R. GONZALES, in his official capacity as United States Attorney General, et al.,

Petitioners,

v.

State of OREGON, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

AMICUS CURIAE BRIEF OF SENATORS RICK SANTORUM, TOM COBURN, M.D., JAMES M. INHOFE, JIM DEMINT, CHRISTOPHER S. BOND, LARRY CRAIG, JUDD GREGG, AND SAM BROWNBACK, AND REPRESENTATIVES STEVE CHABOT, CHRIS SMITH, JACK KINGSTON, JOHN SHIMKUS, JOSEPH R. PITTS, HENRY HYDE, MARK GREEN, TODD AKIN, ROSCOE BARTLETT, JEFF MILLER, STEVE KING, THOMAS PETRI, MARK E. SOUDER, PETE KING, PAUL RYAN, VIRGIL H. GOODE, JR., GENE TAYLOR, JOHN N. HOSTETTLER, AND RALPH HALL IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

Amici curiae have the honor of serving in the United States Congress. Amici Craig, Gregg, Hyde, Smith, Petri and Hall served in Congress at the time of the 1984 amendments to the Controlled Substances Act ("CSA"), 21 U.S.C. § 801, *et seq.* In addition, several of the amici have served or are currently serving on relevant committees of the Senate and House of Representatives, including Congress' Judiciary Committees, the Senate Committee on Health, Education, Labor and Pensions, and Special Committee on Aging, and the House Energy and Commerce Subcommittee on Health. Amicus Hyde has served as Chair of the House Judiciary Committee. Amici Brownback and Hyde have conducted and participated in hearings on the subject of assisted suicide in the United States. Finally, amicus Coburn is a practicing family physician.

In these various capacities, amici are directly concerned with the interpretation and enforcement of the CSA, as well as the relationship between the state and federal governments. Because of the unique perspective they offer in discerning Congress' intent, this brief focuses on the erroneous conclusion of the United States Court of Appeals for the Ninth Circuit that the CSA's legislative history supported its decision.

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than amici and counsel provided financial support for this brief. Further, the consent of the parties to the filing of this *amicus curiae* brief has been obtained and filed with the Clerk of the Court.

SUMMARY OF ARGUMENT

The legislative history to the CSA makes clear that in enacting and later amending the CSA, Congress was concerned with, *inter alia*, the diversion by physicians of federally-controlled substances to illegitimate uses outside the usual course of conduct of medical professionals, and that Congress saw ineffective state regulation as a significant factor in that illegitimate activity. The interpretive rule issued by the Attorney General pursuant to the CSA on November 9, 2001 (the "Interpretive Rule") states that prescribing controlled substances to assist a patient's suicide is not a "legitimate medical purpose." The Rule is entirely consistent with the statute's legislative history.

The Interpretive Rule was issued largely in response to the 1994 Oregon Death with Dignity Act (the "DWDA"), Or. Rev. Stat. § 127.800, *et seq.*, which permits physicians in that state to prescribe and dispense medications, including federally-controlled substances, to assist certain patients in committing suicide. Under the Interpretive Rule, physicians who prescribed, dispensed or administered federally-controlled substances to facilitate a patient's suicide would be subject to denial, suspension or revocation of their registrations with the Drug Enforcement Administration ("DEA") because such conduct "render[ed] [the physician's] registration . . . inconsistent with the public interest." 66 Fed. Reg. 56,607, 56,608 (Nov. 9, 2001).

As seen from the CSA's legislative history, the Interpretive Rule addresses concerns and advances goals that were considered and discussed by Congress in enacting and amending the statute. Further, by issuing the Interpretive Rule, the Attorney General acted in the role that

Congress had envisioned for the federal government. Although the legislative history does not show that Congress contemplated physician-assisted suicide specifically, this does not detract from the Attorney General's authority under the CSA to issue the Interpretive Rule.

The CSA would not apply (and actions taken pursuant to it by the Attorney General would not be authorized) if a state decided to permit assisted suicide but ensured that it would somehow occur without the involvement of DEA-registered physicians prescribing controlled substances. However, that is not the case here. Where a state seeks to permit DEA-registered physicians to assist their patients in committing suicide by prescribing controlled substances, the CSA authorizes the Attorney General to speak to whether this is a legitimate medical purpose. The Interpretive Rule is consistent with the CSA's legislative intent and a reasonable response to the DWDA.

ARGUMENT

Upholding an injunction against enforcement of the Interpretive Rule, the Ninth Circuit mistakenly concluded that the Interpretive Rule conflicted with the CSA's legislative history and that the Attorney General had exceeded his authority by issuing the Rule. *Oregon v. Ashcroft*, 368 F.3d 1118, 1127 (9th Cir. 2004) ("The CSA's legislative record confirms that the Attorney General has exceeded the scope of his authority" under the statute), *cert. granted*, 125 S. Ct. 1299 (2005). To reach this conclusion, the Ninth Circuit ignored the importance of amendments made to the CSA in 1984 and focused primarily on legislative history predating those amendments. *Id.* at

1128. The Ninth Circuit sought to characterize the 1984 amendments as little more than an effort to tidy up "loopholes" in the CSA, but acknowledged that the amendments "authorize[ed] the Attorney General to revoke physician registrations without depending on state licensing boards." *Id.* at 1129 (citing S. Rep. No. 98-225, at 260-62 (1983), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3442-44). What the Ninth Circuit failed to acknowledge was that the Attorney General issued the Interpretive Rule pursuant to this independent authority.

The Ninth Circuit tried to buttress its flawed conclusion by exaggerating the significance of legislative history from 1974 that discussed the role of the Secretary of Health and Human Services ("HHS") in registering practitioners who conduct treatment programs for narcotic addicts, which was entirely unrelated to the issue before the Court. Completing its erroneous analysis, the Ninth Circuit asserted that the legislative record supported its belief that the Attorney General was required not only to review and consider relevant Oregon law (which he did do), but also to solicit and obtain specific input from the state before he could issue the Interpretive Rule; however, this assertion makes little sense in light of the 1984 amendments, which, as the Ninth Circuit recognized, were expressly intended to permit the Attorney General to take action *independent of state authorities.*

The Ninth Circuit's reading of the CSA and its relevant legislative history was overly narrow and ultimately, mistaken. A review of the full legislative history establishes that it squarely supports the Attorney General's interpretation of the CSA and the Interpretive Rule was fully consistent with congressional intent.

I. A REVIEW OF THE LEGISLATIVE HISTORY IS INSTRUCTIVE FOR DISCERNING CONGRESSIONAL INTENT BEHIND THE CSA.

Among the interpretive tools available for determining the Congressional intent underlying a statute is the statute's legislative history. *See, e.g., Barnhart v. Walton*, 535 U.S. 212, 220 (2002); *Dep't of Commerce v. United States House of Representatives*, 525 U.S. 316, 342-43 (1999); *Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon*, 515 U.S. 687, 704-07 (1995); *Negonsott v. Samuels*, 507 U.S. 99, 104-05 (1993). A review of legislative history may be especially appropriate where, as here, the relevant statutory language is broad and susceptible to more than one meaning. *See, e.g., West v. Gibson*, 527 U.S. 212, 219-20 (1999); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 432-35 (1987). Further, this Court has looked to legislative history in determining whether Congress intended for the meaning of terms in a federal statute to depend upon state law, which is also at issue in this case. *See, e.g., Lewis v. United States*, 523 U.S. 155, 170-71 (1998); *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 44-45 (1989); *Dickerson v. New Banner Institute, Inc.*, 460 U.S. 103, 119 (1983).

The Ninth Circuit, as well as the district court below, cited the CSA's legislative history to reach their decisions. However, read together and in context, statements by the sponsors and others in Congress at the time the CSA was enacted in 1970 and amended in 1984, as well as reports from the House, Senate and conference committees, provide ample support for the Interpretive Rule.

II. THE CSA'S LEGISLATIVE HISTORY CLEARLY SHOWS THAT CONGRESS INTENDED THE FEDERAL GOVERNMENT TO PLAY AN ACTIVE ROLE IN REGULATING THE PRESCRIPTION AND DISPENSING OF CONTROLLED SUBSTANCES BY PHYSICIANS.

As seen from the legislative history, Congress viewed the states as the first line of defense under the CSA against the misuse of controlled substances. The legislative history to the CSA also shows that Congress envisioned a central role for the federal government in establishing and enforcing its own standard as to what constitutes such misuse. This role necessarily required that the federal government be able to enforce its standard when a state could not or would not do so.

A. The CSA Enhanced The Federal Government's Long-Standing Role As The Regulator Of Controlled Substances.

While states have traditionally regulated the practice of medicine, the federal government has traditionally regulated the use of controlled substances. *See generally* Jonathon Erlen & Joseph F. Spillane, *Federal Drug Control: The Evolution of Policy and Practice* (2004). Since the 1914 Harrison Act, the federal government has played a significant role in controlling the prescription and dispensing by physicians of toxic, addictive narcotics. Under the Harrison Act, "every person" who imported, manufactured, dispensed or in any way distributed opium, coca leaves or their derivatives, was required to register with the Internal Revenue Service, and pay taxes on such activity. *See* Law of December 7, 1914, ch. 1 (codified as amended at 21 U.S.C. §§ 801-971). Physicians were allowed to dispense or

distribute the drugs regulated by the Harrison Act provided that they registered with the IRS, acted "in the course of [their] professional practice only," and maintained records "of all such drugs dispensed or distributed." *Id.* at ch. 1, § 2(a).

The CSA was Congress' attempt to collect and rationalize the Harrison Act and some 50 other pieces of legislation that had been enacted over the years for the purpose of regulating controlled substances. *See United States v. Rosenberg*, 515 F.2d 190, 196 (9th Cir. 1975); *United States v. Upthegrove*, 504 F.2d 682, 688 n.10 (6th Cir. 1974); *see also* H.R. Rep. No. 91-1444, at 4 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571. Further, Congress "intended the CSA to strengthen rather than to weaken the prior drug laws." *United States v. Moore*, 423 U.S. 122, 139 (1975); *see also United States v. Steinberg*, 525 F.2d 1126, 1133 (2d Cir. 1975).

Congress enacted the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Pub. L. No. 91-513, § 100, 84 Stat. 1236, 1242 (amended 1984). Congress "designed [the CSA] to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs." 1970 U.S.C.C.A.N. at 4589. The CSA created a comprehensive system for federal regulation of such substances, charging the Attorney General and the Bureau of Narcotics and Dangerous Drugs (forerunner to the DEA) with responsibility for administering the system.

Under the CSA, the differing varieties of controlled substances were separated into five categories, ranging

from Schedule I substances, which had no accepted medical use and could be used only in limited situations, to Schedule II, III, IV, and V substances, which had recognized uses and could be manufactured, distributed, and used, subject to the statute's limitations. Pub. L. No. 91-513, § 202 (Schedules I-V), 84 Stat. 1236, 1248-53. Marijuana and heroin were Schedule I substances, for example, while Schedule V included substances such as cough medicine with codeine.[2] Pub. L. No. 91-513, § 202 (Schedules I-IV), 84 Stat. 1236, 1247-1252. The CSA imposed "tighter controls" on the use of "drugs providing serious addiction or abuse problems (those listed in schedules I and II)." H.R. Rep. No. 91-1444, at 4 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4569. The CSA authorized the Attorney General to add, remove or transfer substances to or between the schedules based on procedures established by the statute. Pub. L. No. 91-518, § 201(a)(1), 84 Stat. 1236, 1245 (21 U.S.C. § 802(5)).

Discussing the criteria to be used by the Attorney General in exercising his authority under the CSA to determine the appropriate schedules for different substances, the

[2] Schedule II drugs are highly addictive, but have accepted medical uses. Pub. L. No. 91-513 § 202(b)(2), 84 Stat. 1236, 1247. The two most commonly-prescribed drugs used to assist suicide under the DWDA are pentobarbital and secobarbital, *see* Oregon Dep't of Human Servs., Off. of Disease Prevention and Epidemiology, *Seventh Annual Report on Oregon's Death With Dignity Act* 14 (2005) (*available at*: http://egov.oregon.gov/DHS/ph/pas/docs/year7.pdf); Press Release, Oregon Dep't of Human Servs., Oregon Public Health Servs., *Fewer Oregonians Used Death With Dignity Act in 2001* (Feb. 6, 2002) (*available at*: www.ohd.hr.state.or.us/news/2002/0206pas.htm), which fall into Schedule II, *see* 21 C.F.R. § 1308.12(e). Thus, the DWDA conflicts most directly with the registration requirements and other controls relating to Schedule II drugs.

House Report noted, "Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use, are regarded as indicative of a drug's potential for abuse." 1970 U.S.C.C.A.N. at 4602. Although this reference in the legislative history was not in the context of physician-assisted suicide, it establishes that Congress intended that, in exercising regulatory authority under the CSA, the Attorney General could consider whether a controlled substance was being used to commit suicide.

Besides classifying controlled substances into different schedules, the Attorney General's duties under the CSA included monitoring the use of controlled substances through the registration of manufacturers, physicians, pharmacies, and others. The CSA required all "legitimate handlers" (*e.g.*, physicians) to register with the federal government. Pub. L. No. 91-513, § 302(a), 84 Stat. 1236, 1253. Under the CSA, registration was considered "a matter of right where the individual . . . is engaged in activities involving these drugs which are authorized or permitted under State law." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4590. The CSA authorized the Attorney General to deny, suspend or revoke a physician's registration for three reasons:

1. falsification of an application to dispense, distribute, or manufacture a controlled substance;

2. a felony conviction under state or federal law relating to a controlled substance; or

3. denial, revocation, or suspension of a state license or registration.

Pub. L. No. 91-513, §§ 303(f) & 304(a), 84 Stat. 1236, 1255. Two of these grounds depended in whole or in part on state enforcement and, in 1984, Congress acted to repair "leaks" in the closed system that resulted from this overreliance on state law.

Nonetheless, even before the 1984 amendments, the CSA (and its original implementing regulations[3]) provided clear authority for the Attorney General to regulate physician conduct in prescribing controlled substances. "[T]he scheme of the [CSA], viewed against the background of the legislative history, reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice' .... [In addition,] [o]ther provisions throughout the Act reflect the intent of Congress to confine authorized medical practice within accepted limits." *Moore*, 423 U.S. at 140-42.

B. The 1974 Amendments Distinguished Between The Roles Of HHS And The Attorney General With Regard To Treatment Programs For Narcotics Addicts And Are Irrelevant To The Issue Before This Court.

In the Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124, Congress amended the CSA "to provide for the registration of practitioners conducting

[3] In 1971, the Bureau of Narcotics and Dangerous Drugs promulgated the initial regulations under the CSA. The regulations included standards for prescribing controlled substances: "A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice*." 21 C.F.R. § 1306.04(a) (emphasis added). The Interpretive Rule was based on the Attorney General's interpretation of this regulation. *See* 66 Fed. Reg. at 56,608.

narcotic treatment programs." H.R. Rep. No. 93-884, at 1 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3029. The Narcotic Addict Treatment Act created, *inter alia*, a registration process for the use of controlled substances in treating addicted persons through, for example, methadone maintenance and detoxification programs, that was separate and in addition to the customary registration under the CSA. 1974 U.S.C.C.A.N. at 3029-3030; *see also* 21 U.S.C. § 823(g). The Narcotic Addict Treatment Act is irrelevant to the issue currently before this Court, which concerns the customary registration process under the CSA. Thus, not surprisingly, the Ninth Circuit's conclusion from the legislative history to the 1974 amendments that the Secretary of HHS had ultimate authority to make "'[a]ll decisions of a medical nature'" under the CSA, *Oregon*, 368 F.3d at 1128 (citing 1974 U.S.C.C.A.N. at 3034), conflicts with the language of the statute, *see, e.g.*, 21 U.S.C. § 823(f) ("The *Attorney General* may deny an application for ... registration if *he determines* that the issuance ... would be inconsistent with the public interest.") (emphasis added).[4]

[4] Under the Ninth Circuit's reasoning, the 1974 legislative history would similarly cast doubt on former Attorney General Janet Reno's conclusion that dispensing drugs to assist suicides is a legitimate medical practice under the CSA. *See* Letter from Hon. Janet Reno, Attorney General of the United States, to Hon. Henry Hyde, Chairman, Committee on the Judiciary, United States House of Representatives, at 1 (June 5, 1998) ("Adverse action against a physician who has assisted in a suicide in full compliance with the [DWDA] would not be authorized by the [CSA].").

C. The 1984 Amendments Clarified The Federal Government's Authority To Act Where States Ineffectively Regulated Physician Use Of Controlled Substances.

Although the CSA has been amended many times since 1970, *e.g.*, Narcotic Addict Treatment Act; Drug-Induced Rape Prevention and Punishment Act of 1996 (Pub. L. No. 104-305, § 1, 110 Stat. 3807); Methamphetamine Anti-Proliferation Act of 2000 (Pub. L. No. 06-310, Div. B, Title XXXVI, § 3601, 114 Stat. 1227), the most significant amendments occurred in 1984. The legislative history to the 1984 amendments makes clear that at that time, Congress had become concerned that states were not effectively handling the distribution of controlled substances by physicians and that state law alone was insufficient to prevent the diversion of controlled substances from legitimate medical uses.

Thus, Congress amended the CSA to give the Attorney General additional, independent authority to deny, suspend or revoke a physician's federal registration where he determined that the registration was "inconsistent with the public interest." *See* 21 U.S.C. §§ 823(f) & 824(a)(4), Pub. L. No. 91-513, §§ 303(f) & 304(a)(4), 84 Stat. 1236, 1254. The amendments identified five specific criteria in section 823(f) (and, by reference, section 824(a)) to be used by the Attorney General in determining whether a physician's registration was consistent with the "public interest." Although state law remained an important factor, the Attorney General was also required to consider two criteria wholly independent of state law: namely, "the [physician's] experience in dispensing ... controlled substances" and "[s]uch other conduct which may threaten the public health and safety," 21 U.S.C. § 823(f)(2) & (5).

Notably, since the enactment of the CSA in 1970, the Attorney General has had discretion to determine whether the registration of a manufacturer or distributor of controlled substances was "inconsistent with the public interest." *See* 21 U.S.C. §§ 823(a), (b), (d) & (e); *see also Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 829-30 (D. D.C. 1974), *aff'd*, 530 F.2d 1054 (D.C. Cir. 1976). The 1984 amendments gave the Attorney General the same authority with regard to "practitioners," and registration was no longer "a matter of right" where a physician's conduct complied with state law.

The theme of needing to better control the distribution of controlled substances through physicians by shoring up weaknesses at the state level pervades the legislative history. For example, the House Report accompanying the amendments stated,

> Unfortunately, experience under the [CSA] over the past decade has demonstrated that the same strong regulatory authority to maintain a 'closed' distribution chain does not exist at the practitioner level.... Under current law, the grounds for denial or revocation of the registration of a practitioner are very limited. Indeed, the Attorney General must presently grant a practitioner's registration application unless his State license has been revoked or he has been convicted of a felony drug offense, *even though such action may clearly be contrary to the public interest.*

H.R. Rep. No. 98-1030, at 261-62 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3443-44 (emphasis added). Similarly, Representative Hamilton Fish, a sponsor of the 1984 amendments, stated, "The most serious diversion problem today exists at the retail level. States have primary

responsibility for the licensing of physicians and pharmacists. State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." 130 Cong. Rec. H9680 (daily ed. Sept. 18, 1984).

During discussion in the House, Representative Benjamin Gilman stated that the amendments would "make it easier for the Drug Enforcement Administration to suspend or revoke the authority of physicians and pharmacists who write or dispense prescriptions in a way that is threatening to the public health or safety." *Id.* at H9681. Similarly, Representative Hughes (also a House sponsor) stated that the amended CSA "gives to DEA greater latitude to suspend or revoke the registration of a practitioner [who] dispenses drugs in a manner that threatens the public health and safety." *Id.* at H9679.

At a hearing before a House subcommittee considering the amendments, the DEA testified that the expanded federal authority to revoke a physician's registration was "one of the most important sections of the bill," not only because of inadequate state enforcement but also because "many controlled drug violations . . . are not felonies under state law and therefore cannot be used in a DEA revocation action." *Dangerous Drug Diversion Control Act of 1984*: Hearing on H.R. 5656 before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 403-04 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

In the Senate, sponsor Strom Thurmond noted that, as originally enacted, the CSA

> provides necessary regulation of manufacturers and distributions, but it does not adequately cover the practitioner level of the distribution chain, the level at which 80 to 90 percent of current diversion of drugs into illicit markets takes place. . . . [The 1984 amendments] *expand[] the standards for practitioner registration beyond the current exclusive reliance upon authorization by the practitioner's own jurisdiction.*

130 Cong. Rec. S758 (daily ed. Feb. 2, 1984) (emphasis added).

These amendments expanding federal authority received bipartisan support in Congress. *See, e.g.*, 130 Cong. Rec. H9680-81 (daily ed. Sept. 18, 1984) (statements of Reps. Hughes and Sawyer). The amendments were approved by wide margins, passing in the Senate on February 2, 1984 on a vote of 91 to 1, *see* 130 Cong. Rec. S733, 741, and in the House on September 18, 1984 on a vote of 392 to 1, *see* 130 Cong. Rec. H9742-9743 (daily ed. Sept. 18, 1984). The President signed the legislation, and it became law on October 12, 1984. *See* Pub. L. 98-473, Title II § 501 (1984), 98 Stat. 2068.

The legislative history to the 1984 amendments, along with the amendments themselves, make clear that the "public interest" standard was intended as a requirement independent of and in addition to state felony law and state medical licensing regulations, and that the Attorney General was to determine whether it was in the public interest for a physician to be registered to prescribe controlled substances. The "public interest" provision clarified, if not increased greatly, the Attorney General's existing authority to take action even where a practitioner was in compliance with state law. As the Ninth Circuit was forced to acknowledge, "the 1984 amendments to the CSA . . . extend the Attorney General's authority over

federal registration of practicing physicians . . . " *Oregon*, 368 F.3d at 1129. In issuing the Interpretive Rule, the Attorney General properly exercised this extended authority.

D. The Interpretive Rule Is Based Upon A Reasonable Interpretation Of The CSA's Legislative History.

In light of the legislative intent behind the CSA shown by these congressional reports and comments, it seems difficult to conclude that the Attorney General lacked authority to issue the Interpretive Rule, or that the Rule is somehow contrary to the statute's purpose. In fact, both the 1984 amendments and the Interpretive Rule were federal responses to leaks in the closed system at the state level that allowed physicians to divert controlled substances to improper ends: the 1984 amendments responded to the problem in the states generally, while the Interpretive Rule responded to the problem in a specific state.

Since the 1984 amendments, the following standards have been among those with which a physician must comply to prescribe federally-controlled substances:

1. Any prescription must be issued for a "legitimate medical purpose" and while the physician is acting within the "usual course of his [or her] professional practice," 21 C.F.R. § 1306.04(a); and

2. The physician must not commit acts that cause his or her registration to be inconsistent with the "public interest," 21 U.S.C. §§ 823(f) & 824(a)(4).

With the broad phrases "legitimate medical purpose," "usual course of professional practice," and "public health and safety," the CSA and its implementing regulations leave room for further definition before these provisions can be enforced as a practical matter.

Gaps and ambiguities created by such broad terms can be filled in by the Attorney General based on a reasonable interpretation of their meaning. *See Nationsbank of North Carolina, N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257 (1995) (*citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.* 467 U.S. 837, 843-44 (1984)). To fill in gaps in the CSA and its regulations, the Attorney General can look to the statute's legislative history as one tool for discerning Congress' intent. *See Chevron*, 467 U.S. at 851-53.

Here, in concluding that physicians who prescribe controlled substances to terminate a person's life are not acting for a legitimate medical purpose or in the usual course of their professional practice, and that it is not in the public interest for such physicians to be able to continue to issue prescriptions, the Interpretive Rule fits comfortably within the congressional intent reflected by the relevant legislative history. Besides the statements described in Sections II(A) and (C) above, the legislative history also contains numerous references to the diversion of narcotic and depressant substances out of the legitimate system, the public danger caused by drugs prescribed by physicians for improper reasons, and the large numbers of deaths annually due to overdoses of prescription drugs. *See, e.g.*, 130 Cong. Rec. S9681-82 (daily ed. Feb. 2, 1984).

Notwithstanding the broader public debate regarding the practice of physician-assisted suicide generally, the

dispositive legal question before the Ninth Court was a fairly pedestrian issue of administrative law: "is the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) entitled to deference?" *Oregon*, 368 F.3d at 1131 (Wallace, *J.*, dissenting). Based on legislative history (as well as the statutory language and other sources, *see generally* Memorandum from Deputy Assistant Attorney General Sheldon Bradshaw to Hon. John Ashcroft, "Whether Physician-Assisted Suicide Serves a 'Legitimate Medical Purpose' Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act" (June 27, 2001) ("DAAG Memorandum")[5]), the Attorney General's issuance of the Interpretive Rule was fully within his authority under the CSA and it was entirely reasonable for him to exclude physician-assisted suicide from permissible practices under the CSA and section 1306.04(a). Thus, the Ninth Circuit should have deferred to the Attorney General's interpretation.

E. The Federal Government's Role As Regulator Of Controlled Substances Does Not Displace The States' Role As Primary Regulators Of The Practice Of Medicine.

Congress knew when it enacted the CSA that enforcement of the statute would result in federal regulation of certain aspects of the practice of medicine, which as a general matter had always been considered primarily a state responsibility. Discussing the CSA in 1970, a House Report acknowledged the problem, but concluded that it

[5] The Attorney General relied on the DAAG Memorandum in issuing the Interpretive Rule, and the Rule incorporates it by reference. *See* 66 Fed. Reg. at 56,608.

could not be avoided: "Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last fifty years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinion of federal prosecutors of what constitutes appropriate methods of professional practice." H.R. Rep. No. 91-1444, Part 1, at 51 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4581.

However, Congress never intended to displace the states as primary regulators of physicians, and the CSA was never intended to result in a wholesale nationalizing of the practice of medicine. For example, since its enactment in 1970, the CSA has provided that it does not "occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision [of the CSA] and that State law so that the two cannot consistently stand together." 21 U.S.C. § 903. Even after the 1984 amendments, Congress intended that the DEA "would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications." H.R. Rep. No. 98-1030 pt. B, at 267 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449; *see also* 21 U.S.C. § 823(f)(1). Further, "[r]egistration of a physician under the [CSA] is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation [of] registration only precludes a physician from dispensing substances controlled under the [CSA] and does not preclude his dispensing other prescription drugs or his continued

practice of medicine." H.R. Rep. No. 98-1030, at 267 n.40 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449 n.40.

Thus, for purposes other than the CSA (and leaving aside the issue of whether other federal laws would be implicated), states may have a right to decide whether physician-assisted suicide is a legitimate medical practice. Nonetheless, with regard to prescribing and dispensing federally-regulated substances, the CSA leaves final determination of what constitutes a "legitimate medical purpose" to the Attorney General. Congress realized that not only would federal regulation be concurrent with state regulation but that, in some situations, it would necessarily supersede state law. The result here is that the DWDA must yield to the Interpretive Rule and, like all other DEA-registered physicians in the United States, DEA-registered physicians in Oregon cannot requisition federally-controlled substances to facilitate their patients' deaths.

In determining whether physician-assisted suicide is "inconsistent with the public interest," the Attorney General satisfied the requirement of section 823(f) that he review and consider, *inter alia*, Oregon law. *See* DAAG Memorandum, at 1-2, 6, 14, 20 (reviewing DWDA and its history, legal opinion of Oregon Deputy Attorney General, and effect of proposed interpretation on Oregon physicians). Contrary to the Ninth Circuit's conclusion, the CSA does not require that he "solicit input" from Oregon before issuing the Interpretive Rule, *Oregon*, 368 F.3d at 1129, and, at bottom, the Ninth Circuit merely complains that

the manner in which the Rule was issued was impolitic.[6] Whether this complaint is accurate or not is irrelevant as a legal matter.

Finally, a decision by this Court to affirm the Ninth Circuit's decision will not result in a clean demarcation between the authority of Oregon and the federal government, respectively, to define what constitutes a legitimate medical practice. Instead, Oregon will merely have carved out of the CSA a specific purpose for controlled substances (*i.e.*, assisting suicides) that is governed solely by state law. In enforcing the CSA in Oregon, the federal government will be placed in the position of having to differentiate between "legitimate" and "illegitimate" deaths caused by physicians prescribing controlled substances in the state. Moreover, effective regulation of controlled substances on a national basis will become more difficult if individual states can opt out of the CSA where they disagree with the federal government about proper uses for the substances.

III. THE ATTORNEY GENERAL HAS THE AUTHORITY TO DETERMINE WHETHER PHYSICIAN-ASSISTED SUICIDE VIOLATES THE CSA, NOTWITHSTANDING THE ABSENCE OF SPECIFIC REFERENCES TO THE PRACTICE IN THE LEGISLATIVE HISTORY.

As noted by the Ninth Circuit, much of the legislative history from the CSA's initial enactment reflects a specific

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[6] As noted by the dissent, specific input would be appropriate if and when a particular physician's registration was being reviewed in light of the Interpretive Rule, which is not the situation here. *See Oregon*, 368 F.3d at 1139-40 (Wallace, *J.*, dissenting).

concern with "crack[ing] down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls." *Oregon*, 368 F.3d at 1128 (quoting 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970)). Further, although Congress identified "suicides and attempted suicides" as improper uses of controlled substances, *see* 1970 U.S.C.C.A.N. at 4602, nothing in the history to the 1970 enactment or the 1984 amendments establishes that Congress ever had in mind the specific "practice" of physician-assisted suicide. Nonetheless, these aspects of the legislative history do not support the Ninth Circuit's conclusion that the Interpretive Rule is contrary to the CSA and outside the Attorney General's authority under the CSA.

The application of a statute to circumstances beyond those specifically contemplated by Congress at the time of enactment is not unusual or improper. For example, in *H.J. Inc. v. Northwestern Bell Telephone Co.*, 492 U.S. 229, 245-8 (1989), the Supreme Court acknowledged that Congress' target in enacting the RICO statute "was the perceived need to combat organized crime. But Congress for cogent reasons chose to enact a more general statute, one which, although it had organized crime as its focus, was not limited in application to organized crime." *Id.* at 248. As one congressman noted during debate on the statute, "'Whatever the limited occasion for the identification of a problem, the Congress has the duty of enacting a principled solution to the entire problem. Comprehensive solutions to identified problems must be translated into well integrated legislative programs.'" *Id.* at 246-47 (quoting 116 Cong. Rec. 18913-18914 (1970) (Sen. McClellan)).

Similarly, in *Browder v. United States*, 312 U.S. 335, 339-40 (1941), the Supreme Court upheld a criminal conviction where the defendant used a fraudulently-obtained passport to re-enter the United States. The defendant argued that at the time the statute was enacted, passports were not customarily used by citizens to assure easy re-entry and thus, Congress did not intend to punish the conduct for which he was convicted. The Court stated,

> There is nothing in the legislative history to indicate that Congress considered the question of use [of passports] by returning citizens. Old crimes, however, may be committed under new conditions. Old laws apply to changed situations. The reach of the act is not sustained or opposed by the fact that it is sought to bring new situations under its terms. While a statute speaks from its enactment, even a criminal statute embraces everything which subsequently falls within its scope.

312 U.S. at 339-40 (footnote omitted); *see also Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) ("male-on-male sexual harassment in the workplace was assuredly not the principal evil Congress was concerned with when it enacted Title VII [of the Civil Rights Act of 1964] but statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils"); *United States v. Southwestern Cable Co.*, 392 U.S. 157, 172-73 (1968) (FCC has jurisdiction to regulate community antenna television systems even though when statute creating FCC was enacted in 1934, Congress could not envision development of such systems).

Like the federal statutes in *H.J. Inc.*, *Browder*, *Oncale* and *Southwestern Cables*, Congress drafted the CSA with sufficient breadth such that its language permits reasonable applications not specifically contemplated by Congress. The mere absence of a specific reference to physician-assisted suicide in the legislative history cannot preclude the Attorney General from determining whether it is a legitimate medical practice under the CSA. Demanding proof from the legislative history that Congress envisioned the precise conduct permitted by the DWDA is unreasonable and the purported lack of such "proof" is not a proper ground for enjoining the Interpretive Rule. *See Rust v. Sullivan*, 500 U.S. 173, 189-90 (1991).

If anything, the absence of specific discussions of physician-assisted suicide likely reflects the simple fact that both when the CSA was passed and later amended, such a practice was beyond what Congress contemplated as a reasonable possibility. The 1970 House Report's reference to "misuse of a drug in suicides and attempted suicides" presumes that such use would be a "misuse." In fact, it seems that until former Attorney General Janet Reno issued her written opinion on June 5, 1998 creating an exception from the CSA for Oregon, the general understanding in Congress was that assisted suicide could not be considered a legitimate medical practice.[7]

[7] Certainly the DEA thought so. *See* Letter from Hon. Thomas A. Constantine, Administrator of the Drug Enforcement Administration of the United States To Hon. Henry J. Hyde, Committee on the Judiciary, United States House of Representatives (Nov. 5, 1997) (concluding that prescribing a controlled substance with the intent to assist suicide was not a legitimate medical purpose and would violate the CSA); *see also Hugh I. Schade, M.D., Denial of Application*, 60 Fed. Reg. 56,354 (Nov. 8, 1995) (denying registration on ground of "public health and safety"

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For example, in 1997 Congress passed the Assisted Suicide Funding Restriction Act, which President Clinton signed into law on April 30 of that year. Pub. L. 105-12, 111 Stat. 23. The Assisted Suicide Funding Restriction Act directly prohibits the use of federal funds for the purpose of causing or assisting in causing the death of any individual. *Id.* § 3(a)(1). In passing the Act, Congress stated that its purpose was "*to continue current federal policy* by providing explicitly that federal funds may not be used to pay for items and services (including assistance) the purpose of which is to cause (or assist in causing) the suicide, euthanasia, or mercy killing of any individual." Pub. L. No. 105-12, § 2(b), 111 Stat. 23 (emphasis added). And this remains federal policy today. *See* Health & Human Servs., *Medicare Benefit Policy Manual*, ch. 16, § 20 ("A health care item or service for the purpose of causing, or assisting to cause, the death of any individual (assisted suicide) is not covered" by the Medicare program.) (*available at*: http://www.cms.hhs.gov/manuals/102_policy/bp102c16.pdf). Thus, it seems clear that, apart from the June 5, 1998 opinion, the position of the federal government has consistently been that it will not facilitate suicide.

This reasonable federal policy is consistent with the clear ethical consensus of the medical profession from enactment of the CSA through today. The positions of the American Medical Association and other medical organizations have reflected nearly uniformly the view that physician-assisted suicide is not an acceptable or legitimate medical practice. *See, e.g.*, Am. Med. Ass'n, *Code of Medical*

where physician had prescribed lethal amounts of Darvocet to depressed patient who used them to commit suicide).

Ethics § 2.211 (2005) ("[p]hysician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks" and "[i]nstead of participating in assisted suicide, physicians must aggressively respond to the needs of patients at the end of life"); Editorial, *Deadly milestone: 5 years of assisted suicide*, amednews.com, Apr. 21, 2003 (*available at*: http://www.ama-assn.org/amednews/2003/04/21/edsb0421.htm); Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992) ("Physicians must not . . . participate in assisted suicide[ ]" and "[p]hysician assisted suicide . . . is contrary to the traditional prohibition against using the tools of medicine to cause a patient's death" and includes the "potential for coercive financial and societal pressures on patients to choose suicide."); ANA Position Statement (available at: nursingworld.org/readroom/position/ethics/etsuic.htm); Task Force on the Nurse's Role in End-of-Life Decisions, Center for Ethics and Human Rights (1994) ("[s]uch an act is in violation of the Code for nurses . . . and the ethical traditions of the profession"). Notably, when the CSA was enacted, it was recommended to Congress by a Presidential Commission that under the CSA's regulations, "the definition of legitimate medical use of narcotic drugs [be] primarily . . . determined by the medical profession." H.R. Rep. No. 91-1444, at 21, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4586. In the Interpretive Rule, the Attorney General properly exercised his authority under the CSA by reasonably concurring with the medical profession that physician-assisted suicide is not a legitimate medical practice.

CONCLUSION

For the foregoing reasons, Amici Curiae respectfully request that the judgment of the Ninth Circuit be reversed.

Respectfully submitted,

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